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16 **ELI LILLY AND COMPANY**

17 UNITED STATES DISTRICT COURT  
18 NORTHERN DISTRICT OF CALIFORNIA  
19 SAN FRANCISCO DIVISION

20 STATE OF CALIFORNIA *ex rel.* JAYDEEN ) Case No. 07-cv-04911-CRB  
21 VICENTE and JAYDEEN VICENTE )  
22 Individually, ) Assigned to: Hon. Charles R. Breyer  
23 Relators, ) **DEFENDANT ELI LILLY AND**  
24 vs. ) **COMPANY'S REPLY MEMORANDUM IN**  
25 ) **SUPPORT OF MOTION TO DISMISS**  
26 ELI LILLY AND COMPANY, )  
27 Defendant. )  
28 )

Date: December 7, 2007  
Time: 10:00 a.m.  
Place: Courtroom 8, 19th Floor

**ARGUMENT**

**I. PRIOR PUBLIC DISCLOSURES BAR RELATOR’S FALSE CLAIM ACT CLAIMS**

Without any reasoning or analysis, Relator asserts that her claims are distinguishable from the plethora of media accounts describing Lilly’s alleged promotional activities relating to Zyprexa. Relator contends that these press accounts of Lilly’s promotional activities “disclose nothing like the nature of the fraud alleged here involving Lilly’s LTC sales division.” (Opp. at 3).

Relator’s argument ignores the press accounts described in Lilly’s motion to dismiss. Those prior disclosures include not only a *Daily Mail* story about alleged overuse of Zyprexa in nursing homes, but also a detailed account of the alleged activities of Lilly’s LTC sales division. (MTD at 9:22-10:19 and Request For Judicial Notice (“RJN”), Exs. 17 and 23). This story about alleged LTC sales division activities was not isolated; it also appeared in *Bloomberg News* on March 12, 2007. Reporting on a complaint filed by the State of Montana, *Bloomberg* stated “Lilly created a 280-person sales force ‘to promote Zyprexa exclusively for off-label uses, specifically for long term care facilities to maximize off-label use of Zyprexa sales’ for the elderly.” (Supp. Request for Judicial Notice, Ex. 1).

While Relator contends that public policy dictates a narrow reading of the prior public disclosure bar to False Claims Act suits, public policy actually dictates the dismissal of this action in light of the prior public disclosures. As demonstrated by the press accounts described in Lilly’s Motion to Dismiss, California was clearly on notice of its potential claims and was *already* investigating the matter. There is no benefit to the State in Relator commencing this duplicative action. (MTD at 5:21-26); *see also State of California ex. rel. Grayson v. Pacific Bell Telephone* 142 Cal. App. 4th 741, 746-47 (2006) (“providing cash bounties to freeloaders does not serve the purpose of the FCA to protect the public fisc”).

Neither *City of Hawthorne ex rel. Wohlner v. H&C Disposal Co*, 109 Cal. App. 4th 1668 (2003), nor *U.S. ex rel. Found Aiding the Elderly v. Horizon*, 265 F.3d 1011 (9th Cir. 2001), the only two cases upon which Relator relies, supports a contrary conclusion. In *City of Hawthorne*, the court found that an action alleging a fraud that took place in 1980 was not barred by press

1 accounts of a different fraud that took place in the 1990-95 time frame. 109 Cal. App. 4th at 1684.  
 2 Here, there is no temporal distinction between the misconduct alleged by Relator and the alleged  
 3 misconduct reported in the media. The decision in *Horizon* was already distinguished by *Grayson*,  
 4 142 Cal. App. 4th at 753. As *Grayson* observes, the *qui tam* complaint in *Horizon* alleged that  
 5 nursing home facilities were charging the government for nursing home care that was never  
 6 provided. The defendants argued that surveys and isolated lawsuits regarding substandard care  
 7 barred the *qui tam* action alleging that defendants charged for care never given. *Id.* The court  
 8 rejected the argument and allowed the action to proceed. The *Grayson* court found that the *Horizon*  
 9 decision was based on the finding that a public disclosure of substandard care would not put the  
 10 government on notice that it was charged for non-existent care, as there is a fundamental difference  
 11 between billing for negligent service and billing for fictional service. In this case, however, the  
 12 government was on notice of its potential claims regarding the promotion of Zyprexa: California  
 13 commenced its investigation months before the filing of this complaint. (MTD at 9:14-20).

14 Finally, Lilly's motion to seal certain documents is irrelevant to the prior public  
 15 disclosure bar. That motion made no effort to seal the allegations of this complaint or the extensive  
 16 quotations of documents relevant to those allegations. Rather, the motion only sought to treat the  
 17 documents attached to the complaint in this case consistently with their treatment in the MDL  
 18 proceedings. This Court recognized as much when it denied the motion: "Defendant has not  
 19 submitted any evidence that established that the particular documents attached to the complaint that  
 20 it seeks to seal are confidential . . . [S]imply asserting that the documents are the same or similar to  
 21 documents covered by a protective order in another case does not meet defendant's burden." (Doc.  
 22 No. 37).<sup>1</sup> Indeed, in opposing the motion, Relator acknowledged that "as described in Defendant's  
 23 papers, numerous documents have been published by the New York Times that are similar to the  
 24 documents attached to the complaint." (Opposition to Motion to Seal at 3:12-14); *see also id.* at  
 25 6:13-15. ("Defendant appears to admit that the information is known due to stories and documents

26 \_\_\_\_\_  
 27 <sup>1</sup> Moreover, the documents attached to the Complaint reveal more than Zyprexa promotional activities – they also reveal  
 28 unrelated business activities, sales training methods and the results of Lilly research on physician prescription practices. Seeking the protection of this information does not constitute any admission that Relator's allegations were not widely reported in the media prior to Relator's lawsuit.

published by *The New York Times*”).

**II. RELATOR LACKS STANDING TO PURSUE CAL. BUS. & PROF. CODE §§ 17200 AND 17500 CLAIMS**

Only certain public prosecutors enumerated by statute have standing to bring UCL or FAL claims on behalf of the State of California. They are: (1) the Attorney General, (2) district attorneys, (3) city attorneys, and (4) city prosecutors in any city having a full-time city prosecutor (and only with the consent of the district attorney). Cal. Bus. & Prof. C. § 17204. Recognizing that she is not one of the enumerated public prosecutors, Relator claims she may nevertheless bring a representative action under the UCL and FAL because, as a *qui tam* plaintiff, Relator stands in the shoes of the State of California. (Opp. at 5).

She ignores, however, that neither the UCL nor the FAL authorize *qui tam* actions. As the California Court of Appeal has explained:

By definition, *qui tam* rights have never existed without statutory authorization. As a result, courts have been required to develop criteria to determine whether a given statute in fact authorizes *qui tam* enforcement. Traditionally, the requirements for enforcement by a citizen in a *qui tam* action have been (1) that the statute exacts a penalty; (2) that part of the penalty be paid to the informer; (3) that, in some way, the informer be authorized to bring suit to recover the penalty.”

*Sanders v. Pacific Gas & Elec. Co.*, 53 Cal. App. 3d 661, 671 (1975). In contrast to those statutes that have been recognized as providing *qui tam* rights – such as the California and federal False Claims Act, which expressly allow for statutory fines, penalties, and a bounty for the whistleblower plaintiff – neither the UCL nor the FAL contain any such provisions. To the contrary, the UCL and FAL do not even allow for the recovery of money damages (let alone a bounty), and Proposition 64 prohibits private attorney general actions.

Because the UCL and FAL do not authorize *qui tam* actions, Relator’s reliance on general *qui tam* principles is misplaced. After Proposition 64, the only persons authorized to bring representative actions on behalf of the State of California are those public prosecutors specified in the statute. Accordingly, Relator’s UCL and FAL claims on behalf of the State of California must be dismissed.

1 Nor has Relator pleaded facts sufficient to confer standing as an injured private party  
 2 under the UCL or FAL. To the contrary, Relator's UCL and FAL claims (as pleaded in the  
 3 Complaint) are premised exclusively on injuries allegedly suffered by the State of California and the  
 4 public at large. (MTD at 15:1-5). Such allegations are legally deficient to confer private party  
 5 standing under the UCL and FAL. (*id.* at 15:6-12).

6 Recognizing this failing, Relator now contends, for the first time, that she should still  
 7 be allowed to bring a UCL and FAL claim on behalf of herself and "all California taxpayers whose  
 8 money funded the State Medicaid program." (Opp. at 6). Of course, these newly minted, class  
 9 action allegations of "taxpayer standing" are not pleaded in the Complaint, which is itself grounds  
 10 for rejecting the argument. *Distefano v. Forester*, 85 Cal. App. 4th 1249, 1264-65 (2001). But even  
 11 if they did appear in the complaint, they are legally deficient to confer standing under the UCL or  
 12 FAL.

13 Each of the authorities cited by Relator in support of her "taxpayer standing"  
 14 argument is inapposite because those authorities all involve suits brought by taxpayers against state  
 15 or local governments (and their representatives) under California Code of Civil Procedure 526a,  
 16 which permits California taxpayers to sue "officers of a county, town, city, or city and county to  
 17 obtain an injunction restraining and preventing the illegal expenditure of public funds." *Blair v.*  
 18 *Pitchess*, 5 Cal. 3d 258, 267 (1971); *see also* Cal. Civ. Proc. C. § 526a. But Relator does not bring  
 19 this action against the State of California or other government representative, and none of Relator's  
 20 authorities permit or otherwise support taxpayer standing against a private entity such as Lilly. *Blair*  
 21 5 Cal. 3d at 269 (suit against county officers under Cal. Civ. Proc. C. § 526a); *Waste Management of*  
 22 *Alameda County Inc. v. County of Alameda*, 79 Cal. App. 4th 1223 (2000) (suit against county,  
 23 taxpayer standing rejected); *Vasquez v. State of California*, 105 Cal. App. 4th 849 (2003) (suit  
 24 against state).

25 Moreover, to allow taxpayer standing to pursue UCL or FAL claims would  
 26 undermine the amendments of Proposition 64, which were intended "to prohibit private attorneys  
 27 from filing lawsuits for unfair competition where they have no client who has been injured in fact  
 28 under the standing requirements of the United States Constitution." *Buckland v. Threshold*

1 *Enterprises, Ltd.*, 155 Cal. App. 4th 798, 814 (2007) (quoting Proposition 64, § 1, (e)).

2           Because the standing requirements of Proposition 64 were intended to mirror federal  
3 concepts of constitutional standing, *id.*, federal cases interpreting Article III standing requirements  
4 are relevant in determining whether the standing requirements of the UCL and FAL have been met.  
5 Federal courts have consistently rejected the concepts of taxpayer standing advanced by Relator  
6 here. In *Coyne v. Amer. Tobacco Co.*, 183 F.3d 488 (6th Cir. 1999), for example, the plaintiffs  
7 brought suit against the tobacco industry on behalf of themselves, the State of Ohio, and all Ohio  
8 taxpayers, seeking to recover money expended by the State of Ohio to treat Ohio citizens who suffer  
9 from nicotine addition and other tobacco-related illnesses. *Id.* at 491. The Sixth Circuit held that  
10 plaintiffs' status as taxpayers was insufficient to confer Article III standing because plaintiffs had  
11 "not suffered an injury that is distinct from the injury shared by all Ohio taxpayers and public  
12 employees." *Id.* at 494 (citing *ASARCO, Inc. v. Kadish*, 490 U.S. 605, 613 (1989) (taxpayers lack  
13 standing "where their own injury is not distinct from that suffered in general by other taxpayers or  
14 citizens"))).

15           Here, Relator admits that her alleged injury is identical to the alleged injury suffered  
16 by every other taxpayer or citizen. (Opp. at 6-7 (claiming that "each taxpayer has virtually identical  
17 claims against Lilly for defrauding the State out of millions of dollars by submitting falsified  
18 reimbursement claims to California's Medicaid program for off-label Zyprexa use.")). This  
19 admission dooms Relator's claims for "taxpayer standing."

### 20 **III. RELATOR HAS FAILED TO ALLEGE HER CLAIM WITH PARTICULARITY**

21           As the Ninth Circuit observed in words directly applicable to this case, "[i]t seems to  
22 be a fairly obvious notion that a False Claims Act suit ought to require a false claim. Yet, the  
23 plaintiff-appellant in this case filed his action ... without ever seeing or presenting to a court a single  
24 false claim submitted by the defendants-appellees. This failure is fatal to a *qui tam* action." *U.S. ex*  
25 *rel. Aflatooni v. Kitsap Physicians Services*, 314 F.3d 995, 997 (9th Cir. 2002).

26           Rather than identifying any actual false claim, Relator contends that her allegation of  
27 a scheme is sufficient to satisfy Rule 9(b). This assertion has been repeatedly rejected by the courts.  
28 Like this case, *Aflatooni* involved allegations of medical claims that should not have been

1 reimbursed by the government (in that case, because the services had been “upcoded”). The plaintiff  
 2 in *Aflatooni*, however, like Relator here, never alleged an actual false claim:

3 Aflatooni must establish that a false claim was submitted to the  
 4 government. It is not enough for Aflatooni ‘to describe a private  
 5 scheme in detail but then to allege simply and without any stated  
 6 reason for his belief that claims requesting illegal payments must have  
 7 been submitted. U.S. *ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3rd  
 8 1301, 1311 (11th Cir. 2002). Instead, Aflatooni must show *an actual*  
*false claim* for payment being made to the government.’ *Id.* Evidence  
 of an actual false claim is ‘the *sine qua non* of a False Claim Act  
 violation.’ *Id.*

9 *Id.* at 1002. More recently, the Sixth Circuit expressly considered, and rejected, a *qui tam* complaint  
 10 that alleged an elaborate Medicaid fraud scheme but did not allege any particular false claim having  
 11 been submitted to the government.

12 [A]ccording to Relator, his complaint is adequate if it instead pleads a  
 13 *false scheme* with particularity. We disagree with this analysis  
 14 because it is inconsistent with the FCA and our case law interpreting  
 it. We hold that pleading an actual false claim with particularity is an  
 15 indispensable element of a complaint that alleges a FCA violation in  
 compliance with Rule 9(b).

16 U.S. *ex rel. Bledsoe v. Comm. Health Sys.*, 501 F.3d 493, 504 (6th Cir. 2007) (original emphasis).

17 Relator argues that Rule 9(b) should be relaxed because ““pleading every instance of  
 18 fraud would be extremely ungainly, if not impossible.”” (Opp. at 8:13-14 (quoting U.S. *ex rel.*  
 19 *Franklin v. Parke-Davis, Div. of Wayne Lambert Co.*, 147 F. Supp. 2d 39, 49 (D. Mass. 2001)).  
 20 From this, Relator concludes that “where a relator pleads a complex fraudulent scheme with  
 21 particularity and provides examples of specific false claims submitted to the government, the relator  
 22 may proceed to discovery.” (Opp. at 9:2-4). Whatever the merits of that assertion – which are  
 23 dubious – it has no application to the complaint in this case, as Relator nowhere ever pleads a single  
 24 example of a false claim.

25 Relying on *Franklin*, Relator argues that because she lacks access to documents, she  
 26 is entitled to a relaxed pleading standard. The reasoning from *Franklin* (a case from the District of  
 27 Massachusetts) on which Relator relies for her relaxed pleading assertion has been rejected by the  
 28 First Circuit. U.S. *ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231-233 (1st Cir.



2004).<sup>2</sup> “A qui tam relator may not present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery.” *Id.* at 231. “[A]llowing a relator to plead generally at the outset and amend the complaint at the 12(b)(6) stage after discovery would be at odds with the FCA’s procedures for filing a qui tam action and its protections for the government (which is, of course, the real party in interest in a qui tam action).” *Id.*; see also *U.S. ex rel. Clausen v. Lab Corp. of Am., Inc.*, 290 F.3d 1301 (11th Cir. 2002).

Accordingly:

Underlying schemes and other wrongful activities that result in the submission of fraudulent claims are included in the ‘circumstances constituting fraud or mistake’ that must be pled with particularity pursuant to Rule 9(b). However, ***such pleadings invariably are inadequate unless they are linked to allegations, stated with particularity, of the actual false claims submitted to the government*** that constitute the essential element of an FCA qui tam action. As applied to the FCA, Rule 9(b)’s requirement that averments of fraud be stated with particularity – specifying the ‘time, place, and content’ of the alleged false or fraudulent representations, means that ***a relator must provide details that identify particular false claims for payment that were submitted to the government.***

*Karvelas*, 360 F.3d at 232 (emphasis added).

Likewise, in *U.S. ex rel. McDermott v. Genentech, Inc.*, a qui tam plaintiff sought recovery under the FCA for alleged false submissions of payment to Medicare and Medicaid based on alleged off-label promotion. 2006 WL 3741920 (D.Me., Dec. 14, 2006) (adopted at 2007 WL 2128410 (D.Me. July 24, 2007)). Applying *Karvelas*, the Court refused to lessen the Rule 9(b) pleading requirements and dismissed the FCA claims. Despite the relator’s protests that he allegedly did not have access to all the details required for a claim, the Court stated, “[e]ven if it were ‘impossible’ to bring a qui tam FCA claim based on claims for reimbursement for the use of Rituxan . . . that outcome could well be due to the language used by Congress . . . or to the uniform interpretation of that language by the federal courts.” *Id.* at \*12 fn. 7. The Court concluded that

<sup>2</sup> *Karvelas* has been recognized as “the last word on the issue from the First Circuit.” *U.S. ex rel. McDermott v. Genentech, Inc.*, 2007 WL 3088644, \*1 (D.Me. Oct. 22, 2007) (denying interlocutory appeal in light of recent, definitive ruling on the issue by the First Circuit).



1 “Neither reason for such an outcome necessarily means that the statutory language or the case law  
2 should be disregarded as a matter of public policy, as [relator] seems to suggest.” *Id.*

3 **IV. RELATOR FAILS TO ALLEGE FALSITY, MATERIALITY OR CAUSATION**

4 Relator misconstrues Lilly’s argument that the complaint fails to allege falsity.  
5 Because Medicare and Medicaid regulations mandate reimbursement of pharmaceuticals prescribed  
6 for many categories of off-label use, MTD at 18:8-19:19, the fact that a claim for reimbursement is  
7 made for such an off-label use does not therefore render the claim in any sense “false,” as “[i]t  
8 cannot be an actionable violation of the FCA for an individual to provide truthful information to the  
9 government, in order to allow the government to determine whether or not that information  
10 establishes eligibility for a certain program.” *U.S. ex rel. Burlbaw v. Orenduff*, 400 F. Supp. 2d  
11 1276, 1289 (D.N.M. 2005). Relator’s discussion of the supposed “double-falsity” requirement (Opp.  
12 at 11:15-12:8) therefore misses the mark. Lilly does not contend that a claim must be “doubly-  
13 false,” but instead that it must, at one level or another, constitute a “false” claim. Here, a claim for  
14 reimbursement for off-label use is not inherently “false,” and there are no allegation of false  
15 statements having been made in support of such claims.<sup>3</sup>

16 Moreover, because Medicaid requires the reimbursement of numerous categories of  
17 off-label prescriptions, the alleged off-label nature of the prescriptions at issue was immaterial, as a  
18 matter of law. This immateriality is demonstrated by the undisputed fact that the California  
19 Medicaid forms do not require the claimant to describe the indication for which Zyprexa was  
20 prescribed. *See U.S. ex rel. Hess v. Sanofi-Synthelabo, Inc.*, 2006 WL 1064127, \*7 (E.D. Mo. April  
21 21, 2006) (unpublished) (information not required by the claim form could not be material).  
22 Relator’s only response is the circular assertion that claims were false because of the underlying  
23 diagnosis or the identity of the patient and the assertion, unsupported by any legal authority, that  
24

25 <sup>3</sup> Nor is it sufficient for Relator to dismiss as an “unripe factual dispute” the fact that Drugdex includes the use of  
26 Zyprexa to treat dementia (the primary thrust of the complaint here, which is focused on long-term care facilities) and  
27 therefore that California was obligated to reimburse for such use. Plaintiffs only response is the unsubstantiated  
28 assertion that the complaint alleges more than the use of Zyprexa to treat dementia. The complaint, however, is so  
broad-brushed and so lacks the required particularity that this assertion is impossible to test. Relator is unfettered by  
particularized allegations and the contents of the complaint appear to change based on the nature of the argument to  
which plaintiff is responding.

1 alleged anti-kickback violations “indisputably meet the materiality requirement.” (Opp. at 14:1-5).

2 Finally, even if falsity were alleged, Relator fails adequately to allege causation.  
3 Relator’s sole argument, relying on *Franklin*, is that Lilly allegedly set in motion a chain of events,  
4 the foreseeable outcome of which was the likely submission of a false claim. This notion, adopted  
5 wholesale from tort law, cannot replace the statutory causation requirement of the FCA.

6 Liability under Section 12651(a)(1) requires that a defendant be involved in the  
7 presentment of a claim for payment to the government. *United States v. President and Fellows of*  
8 *Harvard College*, 323 F. Supp. 2d 151, 186 (D. Mass. 2004) (“To ‘cause’ the presentation of false  
9 claims under the FCA, some degree of participation in the claims process is required”). Thus, the  
10 actual presentation or direction or the delegation of the task of presenting claims satisfies the statute.  
11 *See United States v. Mackby*, 261 F.3d 821, 827 (9<sup>th</sup> Cir. 2001); *U.S. ex rel. Drescher v. Highmark,*  
12 *Inc.*, 305 F. Supp. 2d 451, 459 (E.D. Pa. 2004) (“In cases recognizing the liability of a defendant  
13 who ‘causes’ an intermediary to submit a false or fraudulent claim to a government entity, the  
14 factual scenario is typically such that the intermediary is ‘merely a conduit to the transfer of  
15 government funds.’”)

16 On the other hand, merely setting in motion a chain of events that foreseeably leads to  
17 a third party submitting claims forms is not sufficient under the statute. “Mere knowledge of the  
18 submission of claims and knowledge of the falsity of those claims is insufficient to establish  
19 causation under the FCA.” *Harvard*, 323 F. Supp. 2d at 186. In *Harvard*, the court distinguished  
20 between the role of two university officials. The first signed invoices and other documents for  
21 inclusion in government claims; he was found to have “caused” the presentation of false claims. The  
22 second knew of the falsity of the claims, but had no role in the claims process. The court entered  
23 summary judgment in his favor on causation grounds: “even if Shleifer knew or should have known  
24 about the claims process, and even if he knew that false claims were going to be submitted, his  
25 failure to take steps to ensure that Harvard discontinued the submission of the claims does not  
26 constitute ‘causation.’ under the False Claims Act” *Id.* at 189. Likewise, in *United States ex rel.*  
27 *Kinney v. Hennepin County Med. Ctr.*, 2001 WL 964011 (D. Minn. Aug. 22, 2001), physicians who  
28 had signed medical necessity certification on ambulance run sheets were not liable under the FCA

1 when a different entity, the Hennepin County Medical Center, sought reimbursement for ambulance  
 2 runs that were not medically necessary; the defendants had never delegated to the Medical Center  
 3 the responsibility or authority to submit claims and had no control over the claim process. *Id.* at \*9.

4 Relator's overbroad causation theory not only ignores the causation rulings directly  
 5 applicable to the False Claims Act, but it also runs afoul of the statutory language. A defendant may  
 6 be held liable either for "presenting or causing to be presented" a false claim (Section 12651(a)(1))  
 7 or for making a false statement or record that causes a false claim to be paid (Section 12651(a)(2)).  
 8 These are two different liability schemes – knowing presentation or knowing falsity – and they make  
 9 plain that for a defendant not engaged in the presentation of a claim, there is a requirement that that  
 10 defendant have made a false statement. Relator's causation theory impermissibly eliminates the  
 11 falsity requirement in an action against a defendant not involved in the actual presentation of a  
 12 claim. Here, Lilly was not involved in the presentation of a claim, which resulted instead from a  
 13 series of independent decisions by learned intermediaries. Lilly cannot be held liable under Section  
 14 12652(a)(1).

### 15 CONCLUSION

16 For all of the reasons expressed above and in Lilly's Motion to Dismiss, Relator's  
 17 complaint should be dismissed.

18 Dated: November 21, 2007

SIDLEY AUSTIN LLP

20 By: /s/ Timothy T. Scott

21 Attorneys For Defendant  
 22 ELI LILLY AND COMPANY  
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